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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,271	12/28/2000	Clifton A. Alferness	10057-701.201	8995

66854 7590 04/30/2009

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ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CLIFTON A. ALFERNESS and DAVID M. KAYE

Appeal 2009-0122
Application 09/751,271
Technology Center 3700

Decided:[1] April 30, 2009

Before TONI R. SCHEINER, ERIC GRIMES, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 25-30, all the claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The present invention "relates to a device . . . and method for constricting a mitral valve annulus to correct mitral valve dilation" (Spec. 1: 5-7).

Claims 25-30 read as follows:

25. A method of treating dilated cardiomyopathy of a heart of a patient, the method including the steps of:

providing a constriction device formed of resilient material having an unstressed C-shape configuration with an effective radius less than a dilated mitral valve annulus and a cross sectional dimension for being received within the coronary sinus of the heart; and

advancing the constriction device into the coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart.

26. The method of claim 25 wherein the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer.

27. The method of claim 26 including the further steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient.

28. The method of claim 26 including the further step of placing a cylindrical sheath within the coronary sinus of the heart of the patient, the sheath having a cross-sectional dimension for receiving the introducer and constriction device, and wherein the advancing step includes the step of guiding the introducer and constriction device into the coronary sinus within the sheath.

29. The method of claim 28 including the further steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and sheath from the patient.

30. The method of claim 29 including the further step of retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device.

The Examiner relies on the following evidence:

Houser et al. US 2002/0035361 A1 Mar. 21, 2002

The Examiner rejected the claims as follows:

- Claims 25-27 under 35 U.S.C. § 102(e) as anticipated by Houser.
- Claims 28-30 under 35 U.S.C. § 103(a) as unpatentable over Houser.

THE ISSUE: ANTICIPATION

The principal issue raised by this rejection is whether the Examiner has established that Houser describes advancing a C-shaped constriction device, with an effective radius less than a dilated mitral valve annulus, into the coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart. A secondary issue is whether the Examiner has established that Houser describes releasably coupling the constriction device to a flexible introducer.

FINDINGS OF FACT

FF1 Appellants claim a method of treating dilated cardiomyopathy of a heart patient by providing a C-shaped constriction device formed of resilient material with an effective radius less than the annulus of a dilated mitral valve, and advancing the constriction device into the coronary sinus

of the heart until the constriction device at least partially encircles the mitral valve of the heart (claim 25).

FF2 The word "encircle" is a transitive verb meaning[2]

1 : to form a circle around : SURROUND
2 : to pass completely around

FF3 Claim 26 depends from claim 25 and specifies that "the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer." Claim 27 depends from claim 26 and specifies "releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient."

FF4 The word "coupling," when used as a verb, as in claim 26, has several ordinary meanings, including[3]

1 a : to connect for consideration together **b** : to join for combined effect
2 a : to fasten together : LINK **b** : to bring (two electric circuits) into such close proximity as to permit mutual influence

FF5 Ordinary meaning **2 a** is consistent with the Specification's description of a "coupling arrangement." Figure 5 of the Specification, reproduced immediately below, shows a cross section of a preferred embodiment of a "releasable coupling arrangement" between a constriction device and an introducer (Spec. 4: 28-30).

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[2] From Merriam-Webster's Online Dictionary, at http://www.merriam-webster.com/dictionary/encircle
[3] From Merriam-Webster's Online Dictionary, at http://www.merriam-webster.com/dictionary/couple(2)

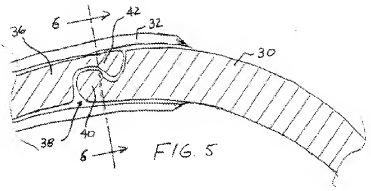

Figure 5 depicts "coupling arrangement 38" which "includes a coupling interlock mechanism 40 at the proximal end of the mitral valve therapy [constriction] device 30 and a complimentary [sic] interlock mechanism 42 at the distal end of the introducer 36" (*id.* at 7: 12-14). The coupled constriction device and introducer may be guided into position through "elongated sheath [32] . . . which is first advanced into the coronary sinus" (Spec. 3: 20-24). "The sheath preferably takes the form of a double-wound polyester catheter . . . dimensioned for receiving the mitral valve therapy [constriction] device 30 and the introducer 36" (*id.* at 6: 23 to 7: 11). Rotating the introducer relative to the constricting device uncouples the introducer from the device, allowing the introducer to be removed from the patient, while leaving the constricting device in place in the coronary sinus (*id.* at 3: 25-26; 7: 16-19).

FF6 The Examiner rejected claims 25-27 under 35 U.S.C. § 102(e) as anticipated by Houser.

FF7 Houser discloses "methods and apparatus that are configured to mechanically modify the geometry and operation of a heart valve and annulus of a valve" (*id.* at ¶ 10). According to Houser,

> These mechanical resizing systems may generally entail the positioning, deployment, and securing of one or more clips to

> bring the annular edges of a valve, e.g., a heart valve, or opening together to correct for valvular regurgitation. This would typically result in the reduction of the effective diameter of the valve or opening. The clip is preferably made of superelastic or shape memory material . . . capable of providing a permanent compressive spring force.

(Houser ¶ 115.)

FF8 Upon deployment, the mechanical resizing clips may be secured in various positions:

> The clips may be attached to the annulus of tissue surrounding the valve . . . ; they may be attached to opposing sides of the valve and preferably have a compressive spring force to draw or cinch the sides of the valve towards one another. The clips may be configured to traverse directly over the valve itself, but they are preferably configured to lie partially over the periphery of the valve to prevent obstruction of the valve channel.

(Houser ¶ 14.)

Alternatively, "circumferential" clips are configured to "surround the periphery of the valve and provide an inwardly biased spring force . . . to at least partially cinch the valve" (Houser ¶ 122).

FF9 A "circumferential clip" is illustrated in Houser's **Figure 27A**, reproduced immediately below:

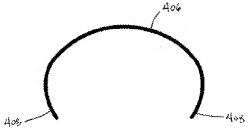

FIG. 27 A

Figure 27A "shows circumferential clip **406** having opposing members **408**. This clip variation, preferably made of a shape memory alloy, . . . may be inserted into the tissue surrounding a valve. This clip may surround [about 50% to 75% of] the periphery of the valve and provide an inwardly biased spring force provided by opposing members **408** to at least partially cinch the valve" (Houser ¶ 122).

FF10 Houser's **Figure 28** shows a cross-sectional superior view of heart section **390** with circumferential clip **406** deployed in the heart tissue. Figure 28 is reproduced immediately below:

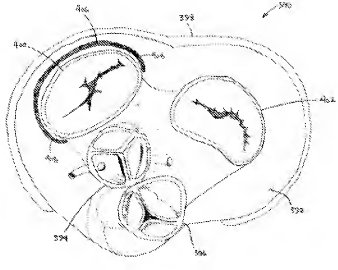

Figure 28 is a cross-sectional superior view of heart section **390**, showing the tricuspid valve **400**, the mitral valve **402**, the ascending aorta **394**, the pulmonary trunk **396**, and the coronary sinus **398**. Circumferential clip **406** is deployed in the tissue **392** surrounding tricuspid valve **400** (Houser ¶ 122). "As shown, opposing members **408** preferably provide the inwardly biased spring force to at least partially cinch valve **400**" (*id.*).

FF11 As shown in **Figures 27A** and **28**, Houser's circumferential clip **406** has an "unstressed C-shape configuration" as required by the present claims.

FF12 According to Houser, "[t]he clip may be delivered and placed over or around the valve using a variety of different methods, e.g., endoscopically, laparoscopically, or through other conventional methods such as open-heart surgery. A preferable method . . . is to deliver the clip through the vasculature using a delivery catheter and/or guidewire" (Houser ¶ 128).

FF13 Once the catheter has reached the target site, the clip may be advanced through, and urged out of, a delivery port by a plunger and/or stylet (Houser ¶¶ 130-132).

FF14 Houser's **Figure 39**, reproduced below, shows the distal end of a deployment catheter:

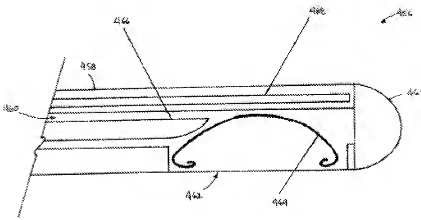

Figure 39 shows the distal end of a deployment catheter with delivery port **462** "defined along a distal length of catheter body **458** proximally of distal tip **461**" and stylet **466** (Houser ¶ 132). According to Houser, "[c]lip **464** may be any of the variational shapes described above" (*id.*).

FF15 "[O]ne exemplary method is to introduce deployment catheter **478** into the coronary vasculature through, e.g., the jugular vein, and into the superior vena cava SVC. From there, tricuspid valve TV may be treated or the mitral valve MV may be treated" (*id.* at ¶ 134).

FF16 "Alternatively, a catheter may be inserted into the coronary vasculature, particularly the coronary sinus, via the aorta to deliver the clip" (Houser ¶ 138). Delivery and deployment of one type of clip to the mitral valve, through the coronary sinus, is depicted in **Figures 42A** through **42C**, reproduced below:

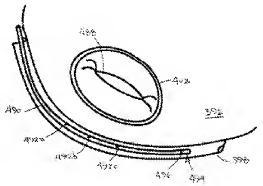

FIG. 42 A

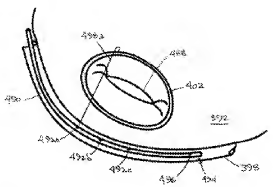

FIG. 42 B

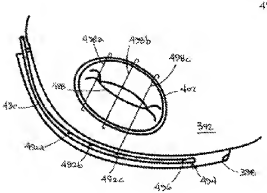

FIG. 42 C

Figure 42A shows "[a] cross-sectional superior view of mitral valve opening **488** of mitral valve **402**" with "[d]elivery catheter **490** . . . inserted into the coronary sinus **398** and positioned adjacent to mitral valve **402** such that delivery ports **492*a***, **492*b***, **492*c*** are preferably facing in apposition to mitral valve **402**" (*id.*). "Once proper orientation has been determined, a first clip **498*a*** . . . may be urged out of delivery port **492*a*** by a plunger and stylet . . . and pushed through a wall of the coronary sinus **398** and through the adjacent heart tissue **392**, as shown in **FIG. 42B**" (*id.* at ¶ 139). **Figure 42C** shows clips **498*a*** and **498*b*** fully engaging the tissue surrounding mitral valve **402** (*id.*).

PRINCIPLES OF LAW

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

In addition, "[t]he ordinary and customary meaning of a claim term may be determined by reviewing a variety of sources. Some of these sources include the claims themselves; dictionaries and treatises; and the written description, the drawings, and the prosecution history." *Brookhill-*

Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003) (citations omitted).

The purpose of giving claims their broadest reasonable interpretation during examination is to reduce "the possibility that claims . . . will be given broader scope than is justified" by the prior art. *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004) (internal citations omitted).

ANALYSIS

Claim 25

The Examiner finds that Houser's "embodiment[s] of figures 27A and 27B are not unlike appellants[']" (Ans. 4), and concludes that "it is within a reasonably broad interpretation that any of the clips disclosed such as that shown in figures 27A and 27B can be delivered via the coronary vasculature" (*id.*).

Appellants contend that Houser "fails to disclose a device with the recited unstressed effective radius" (App. Br. 7).

This argument is not persuasive. Houser's C-shaped circumferential clip (**Figure 27A**; **FF 9**; **FF10**) has an "inwardly biased spring force" that "at least partially cinches the dilated valve" (**FF10**). Appellants have not explained how Houser's circumferential clip could cinch the valve unless it had an unstressed effective radius less than the dilated valve.

In addition, Appellants contend that the Examiner "is looking at one Houser embodiment for the device and another for the delivery method" (Reply Br. 3). Appellants argue that Houser "mentions the coronary sinus delivery of clips that can be placed across the top of the mitral valve outside of the coronary sinus, such as shown in Figures 42[A-D], without partially encircling the mitral valve" (*id.*), but "never says that clip 406 can or should

be delivered to that location via the coronary sinus or that it would partially encircle the mitral valve while it was in the coronary sinus if it were delivered by that route" (*id.*). Finally, Appellants contend that "deployed clip 406 of Figures 27A and 27B lies outside of the coronary sinus" (*id.*).

These arguments are not persuasive. Houser discloses clips in a large number of "variational shapes," and primarily uses the term "clip" generically when discussing clip deployment. For example, Houser teaches that clips can be delivered in various ways, but it is preferable "to deliver the clip through the vasculature using a delivery catheter" (**FF12**). In addition, Houser teaches that "any of the variational shapes of clips" may be delivered to a site through a deployment catheter and released through a delivery port located on the side of the catheter (**FF14**). While Houser provides an example in which a clip with a variational shape other than circumferential is delivered to the mitral valve through the coronary sinus (**FF16**), there is no indication that only that particular type of clip can be delivered in that manner. We agree with the Examiner that Houser discloses deploying "any of the variational shapes" of clips to the mitral valve through the coronary sinus.

Moreover, it is irrelevant that Houser's circumferential clip is ultimately deployed in the annulus of the valve rather than in the coronary sinus itself, because claim 25 does not require final deployment. Claim 25 merely requires advancing the device into the coronary sinus until the device at least partially encircles the mitral valve (**FF1**). It is reasonable to conclude that a circumferential clip in a deployment catheter will lie alongside of and partially encircle the mitral valve when the catheter is in the

coronary sinus and in position to deploy the clip to the mitral valve (*see e.g.*, **Figure 42 A-C**; **FF16**).

Claims 26 and 27

Claim 26 depends from claim 25 and specifies that "the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer." Claim 27 depends from claim 26 and specifies "releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient."

The Examiner finds that Houser's "plunger/introducer assembly . . . can be considered a releasable coupling, for when the plunger force[s] the clip out of the housing they are released from contact. When they reside in the introducer at some point they are contacting each other in a connecting manner" (Ans. 5).

Appellants contend that "[t]here is no releasable coupling between the plunger and the clip" in Houser. Rather, "a plunger 448 at the distal end of a stylet 450 simply pushes the clip out [of] the end of the catheter" (App. Br. 8).

Appellants' argument is persuasive. Both the present invention and Houser describe embodiments in which the constriction device/clip is guided into the coronary sinus using a catheter or catheter-like flexible sheath (**FF6**, **FF12**, **FF13**, **FF14**). In Houser, the constriction device/clip is placed in a catheter, the catheter is moved into position, and the clip is urged out of the catheter with a plunger or stylet (**FF16**). While Houser's plunger/stylet pushes the clip through and out of the catheter, just as the introducer of the

present invention pushes the constriction device through the flexible sheath (or simply through the coronary sinus if no sheath is used), there is no indication that Houser's clip is fastened to the plunger/stylet in any way. We conclude that the recitation "releasably coupling the constriction device to . . . [the] introducer" in claim 26 is not broad enough to include mere contact between Houser's plunger/stylet and clip, given the description of releasable coupling in the specification (including the drawings), and the ordinary meaning of the term "coupling" (i.e., fastening) most relevant to that description (**FF4**, **FF5**). Again, the purpose of giving claims their broadest reasonable interpretation during examination is to reduce the possibility that the claims will be given broader scope than is justified. *See Bigio*, 381 F.3d at 1324. The purpose is not to stretch the interpretation of a claim limitation beyond what would be reasonably understood by the skilled worker in the light of the Specification, to read on a prior art structure which could possibly, but not reasonably, be covered by it.

CONCLUSIONS OF LAW: ANTICIPATION

The Examiner has established that Houser describes advancing a C-shaped constriction device, with an effective radius less than a dilated mitral valve annulus, into the coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart, as required by claim 25.

However, the Examiner has not established that Houser describes releasably coupling the constriction device to a flexible introducer, as required by claims 26 and 27.

Accordingly, the rejection of claims 25-27 as anticipated by Houser is affirmed with respect to claim 25, but reversed with respect to claims 26 and 27.

ISSUE: OBVIOUSNESS

The issue raised by this rejection on appeal is whether the Examiner has established that Houser teaches or suggests releasably coupling the constriction device to a flexible introducer.

FINDINGS OF FACT

FF17 The Examiner rejected claims 28-30 under 35 U.S.C. § 103(a) as unpatentable over Houser.

FF18 Claim 28-30 depend directly or indirectly from claim 26, and therefore also require "releasably coupling the constriction device to an elongated flexible introducer" (claim 26).

PRINCIPLES OF LAW

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). Obviousness requires a suggestion of all the elements in a claim, *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003), and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

ANALYSIS AND CONCLUSIONS OF LAW

Claims 28-30 require "releasably coupling the constriction device to an elongated flexible introducer," a limitation we have already determined is not taught by Houser. The Examiner has not otherwise addressed this

limitation, and therefore has not established that Houser provides a reason or suggestion to releasably couple the instant constriction device to a flexible introducer.

Accordingly, the rejection of claims 28-30 as unpatentable over Houser is reversed.

SUMMARY

- The rejection of claims 25-27 under 35 U.S.C. § 102(e) as anticipated by Houser is affirmed with respect to claim 25, and reversed with respect to claims 26 and 27.

- The rejection of claims 28-30 under 35 U.S.C. § 103(a) as unpatentable over Houser is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED-IN-PART

cdc

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